

*United States Court of Appeals
for the Second Circuit*

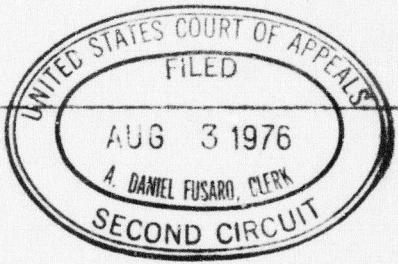


**APPELLANT'S
REPLY BRIEF**

UNITED STATES COURT OF APPEALS
FOR THE
SECOND CIRCUIT
DOCKET NO. 76-7298

JOHN L. GRADY & FATIMA GRADY,
PLAINTIFFS-APPELLANTS
VS.
RODERICK A. MCLEAN,
DEFENDANT-APPELLEE

APPEAL PETITION FOR REVIEW FROM THE
UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT
OF NEW YORK



REPLY BRIEF: OF PLAINTIFF-APPELLANT

REPRESENTATIVE: *(John L. Grady)*

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STATEMENT OF ISSUES PRESENTED FOR REVIEW

1. Dismissal Of Claim Because Of The Lack Of Subject Matter Jurisdiction, Where The Merits Were Not Properly Heard, Nor Given The Proper Judicial Notice.
2. Review Of The Entire Case With All Of It's Merits, Prior To Final Judgement In The Court Of Appeals.
3. The Necessary Required Question Of Federal Law Determining If The Defendant Doctor Roderick A. Mclean, Was On September 5, 1973, Authorized By The Distributor Or Whoever; To Dispense The New Drug Provera(Medroxyprogesterone Acetate), And Whether Provera At That Time Was A New Drug.
4. Review Of Appellee's Brief Page No. 2, No Mention Was Made Of The Appellee's Claimed Filing With The U.S. District Court Clerk On His Initial, And Required Answer To The Summons, In The Docketed Enteries Dated April 19, 1976.
5. Review Of The Non-Responsiveness Of The Pleadings Of The Defense Counsel's For The Defendant, And The Checker Game Of Moving From One To Another, And The Withdrawal Of The Defense's Motion To Dismiss In His Letter Dated July 27, 1976, And Other Dilatory Pleadings By The Defense.

STATEMENT OF THE CASE

This appeal arises out of a Judgement Order dismissing plaintiff's claim on May 10, 1976, signed by Judge Edmund Port on May 12, 1976, and docketed in the Court Record on May 13, 1976, for then it was known to be final for appeal. It was an action for medical malpractice under federal law, because of the defendant's gross negligent breach; in knowingly dispensing a hazardous, unapproved, a drug deemed to be unsafe and ineffective for it's stated use, by the FDA. This drug Provera(medroxyprogesterone acetate), was prescribed by the defendant doctor, although he was aware of the plaintiff's health problem of infection in her reproduction organs.¹

There also exists the question; of whether the defendant doctor was authorized to dispense the experimental drug, that would constitute a violation of; dispensing drugs without a prescription, that becomes another necessary required question of law, that must be reviewed by the Court of Appeals.

This case was actually dismissed in the lower Court, because of the lack of judicial notice of fair hearing and argument of the plaintiffs merits, and then judged as; " lacking subject matter jurisdiction. "

The 1962 Act of Food & Drug amended, Sec. 201(p)-(1) of the 1938 Act; defines a new drug as; a drug not generally recognized among experts as, safe and effective for it's intended use,² also new drugs that are misbranded are in violation of the Food, Drug, & Cosmetic Act, giving primary jurisdiction to the FDA for judicial subject matter jurisdiction to Federal Courts, do to the commerce clause.

The provision of the section prohibiting the dispensing of certain potentially harmful drugs transported into interstate commerce, with, or without a prescription, applies to the act of dispensing drugs by licensed physicians as well.³ Prescription drugs on the market are subject to efficacy requirements of Chapter 21, Sec. 355 Food, Drug, & Cosmetic Act. However, the former drugs are generally recognized as safe and effective by experts,

they are not experimental drugs under a non-approval application.⁴

In the case of U.S. Vs. Dotterweich, Judge Whittaker, a District Judge at the time; said to a druggist in sentencing the prisoner; " that there is no need to refer to the legislative history of the Food & Drug Act, to construe the statute, for the Supreme Court has on several occasions held that; the purpose of the legislation is the protection of the people from dangerous products which are shipped in interstate commerce.⁵" and as shown, this federal protection right is directed at Distributors, Pharmacist, and Doctors, when such drugs as Provera(medroxyprogesterone acetate), are unsafe, or misbranded, and is either distributed, or sold, or dispensed, and especially when under federal regulation, and in accordance to which of the three the tort-feasor may be.

Where federal secured rights are invaded, and injury has resulted from the operation of the statute, federal protection cannot be denied under the Constitutional laws of the United States; and by various Acts of Congress made in pursuant thereof.⁶

Any construction of state law, defeats the cause of the plaintiffs federal rights, relevant to Provera under title 21, Food, Drug & Cosmetic Act that grants to U.S. Courts jurisdiction over all suits, and actions at law brought to enforce any liability, or duty created by this statute and title, and where provisions are made for a general right to sue.⁷ Notwithstanding the federal interest in uniform, national regulation.⁸

The Supreme Court in the 1970 decision in Association of Data Processing Service Organizations, Inc. v. Camp,^{24.1} the Supreme Court continued to rewrite the law of standing in a direction that broadens previous notions of who has standing. The lower Court had denied standing on the ground that the plaintiffs had no legally protected interest, that view was based on an earlier Supreme Court decision,^{24.2} the Court rejected it, saying: " The legal interest test goes to the merits.⁹ For determination of this case the merits must be heard for jurisdiction, this was not completed in lower Court.

The denial of the plaintiff's right under Rule 7(b), for a speaking

motion, prevented the plaintiffs from seeking leave to amend the jurisdictional point, was prejudicial error in law affecting the legal rights of parties, and the plaintiffs.¹⁰

The patient of course had to give her consent with full knowledge of the risks involved in the use of the drug Provera, before the physician, defendant had a right under federal law(FDA), and the statute to prescribe it,

The defendant doctor McLean did not get the plaintiff's consent to use the drug, or to prescribe the drug Provera for her. Not only did the defendant not take precautions in prescribing the drug Provera for the plaintiff he would not even tell the plaintiff patient, what the drug was, when the plaintiff patient asked the defendant. It is a liable cause for the defendant doctor to dispense an unsafe drug as Provera, knowing fully of the plaintiff's health problem in her reproduction organs(see Exhibit Item No. VI, from the lower Court records.

The federal question jurisdiction in this case necessarily draws into question the interpretation, or application of federal law. For the scope of jurisdiction extends to the Constitution. In Section 19, of Federal Question Jurisdiction, in the Osborn case, Justice Marshall observed that " when a question to which the judicial power of the Union is extended by the Constitution, forms an ingredient of the original cause, it is in the power of Congress to give the Circuit Courts jurisdiction of that cause, although other questions of fact or of law may be involved in it."

STATEMENT OF PRECISE RELIEF SOUGHT: CONCLUSION.

1. Money Demanded In The Complaint, Of Both Prayers Of Relief.
2. Trial Remedy, Or Relief In The U.S. Court Of Appeals, Or The Federal Court, Because Of The Dependency Of Federal Cause Of Injury.
3. Declaratory Relief When Its Needed In The Court Of Appeals.

4.

Jedda L. Grady
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AUG 3 1970

MR. JOHN L. GRADY
MRS. FATIMA GRADY
PLAINTIFFS
VS.
DR. RODERICK A. McLEAN
DEFENDANT

RECEIPT FOR CERTIFIED MAIL

SENT TO:
Martin-Ganotis-Amsler & Brown
STREET AND NO.:
499 S. Warren St. Attorneys
At Law
ZIP CODE:
Syracuse, N.Y. 13202

OPTIONAL SERVICES FOR ADDITIONAL FEES

RETURN 1. Shows to whom and date delivered
RECEIPT 2. Shows to whom, date and where delivered
SERVICES With restricted delivery

RESTRICTED DELIVERY

SPECIAL DELIVERY (extra fee required)

PS Form 3800 NO INSURANCE COVERAGE PROVIDED
Jan. 1970 NOT FOR INTERNATIONAL MAIL

No. 37592

Please file as neglect

Proof Of Service
on other party

b7c -
Deals -